ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Member States shall agree the final educational material with the Marketing Authorization Holder (MAH) prior to launch of the product in their territory.

The Member States shall ensure that the MAH provides all physicians who are expected to prescribe or use Vyndaqel with a healthcare professional educational pack containing the following:

- The Summary of Product Characteristics
- The Physician Information Leaflet

The Physician Information Leaflet should contain the following key messages:

- The need to counsel patients on important risks associated with Vyndaqel therapy and appropriate precautions when using the medicine, particularly the avoidance of pregnancy and the need for effective contraception.
- That patients should be advised to contact their doctor about adverse events and that physicians/pharmacists should report suspected adverse reactions to Vyndaqel since there is limited knowledge about the clinical safety due to the rare nature of transthyretin amyloidosis.
- That physicians are encouraged to enter patients in the Transthyretin Amyloidosis Outcome Survey (THAOS) and provided with details how to enroll patients into this international disease registry.
- The existence and scope of the Tafamidis Enhanced Surveillance for Pregnancy Outcomes (TESPO) program and the details how to report pregnancies in women who are being treated with Vyndaqel.